

## REMARKS

Claims 1-6, 12, 15, 16, 43, 47-48, 59-61, 140-146 and 174-176 are pending in this application. Claims 140-146 and 174-176 are withdrawn by the examiner. Claims 1-6, 12, 15, 16, 43, 47, 48, and 59-61 are currently under examination. Claims 1, 3, 43, and 59 are amended for clarity, as discussed herein. Support for the amendments to claims 1, 43, and 59 reciting "forming a strong interface between the polyethylene and the piece" can be found throughout the specification, for example, see page 12, lines 1-8; paragraph bridging pages 12 and 13; page 21, lines 18-19; and page 22, lines 13-15. Therefore, no new matter is introduced. The Office Action is discussed below:

### ***Obviousness Rejections:***

On pages 2-8 of the Office Action, the examiner has maintained the obviousness rejections of the claims as described below:

On pages 3-5 of the Office Action, the examiner rejects Claims 1-4, 6, 12, 15, 16, and 59-61 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* (PN 5,879,400) in view of Ashby *et al.* (PN 5,989,472).

On pages 5-6 of the Office Action, the examiner rejects Claims 43 and 48 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* in view of Ashby *et al.* and Johnson (PN 4,971,761).

On pages 6-7 of the Office Action, the examiner rejects Claim 5 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* in view of Ashby *et al.* as applied to claim 1 above, and further in view of Kagiya *et al.* (PN 3,894,928).

On pages 7-8 of the Office Action, the examiner also rejects Claim 5 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* in view of Ashby *et al.* as applied to claim 1 above, and further in view of Patel (PN 4,164,458).

On page 8 of the Office Action, the examiner rejects Claim 47 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* in view of Ashby *et al.* and Johnson as applied to claim 43 above, and further in view of Patel.

In response to the arguments, filed on February 13, 2009, on pages 9-10 of the Office Action, the examiner asserts that:

Ashby discloses compression molding polyethylene powder to a metal component (refers to col. 3, lines 3-8) and Merrill discloses a method for forming a medical prosthesis in which a fabricated polyethylene article is irradiated using electron irradiation while at a temperature above the melting temperature (refers to col. 2, lines 30-50).

Applicants respectfully disagree with the examiner and submit that a combination of the cited references does not teach or suggest all claim limitations of the independent claims 1, 43 or 59. Thus, all independent claims and the claims depending therefrom are nonobvious over the cited references, as mandated in the MPEP that:

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

See, MPEP § 2143.03 at 2100-142 (Rev. 6, September 2007).

Applicants also submit that the claimed invention is not a mere combination of compression molding of polyethylene by Ashby and irradiation according to Merrill while the polyethylene is at melt, as asserted by the examiner. Even if combined, the two methods as disclosed by Ashby and Merrill, would not yield the claimed medical implant forming an interlocked hybrid material having an interface between the compression molded polyethylene and the piece. Applicants also clarify, according to the claimed invention the crosslinking of a compression molded polyethylene of the hybrid material provides a strong interface between polyethylene and the piece (for example, metal), which is not possible by mere combination of the processes disclosed in the cited references. According to the claimed invention, subsequent melting of the crosslinked hybrid material is done to improve oxidative stability of the irradiated polyethylene so that in the long term oxidation does not compromise the interface strength. Neither Ashby nor Merrill provides any suggestion to heating a compression molded hybrid material above the melting point of the polyethylene after irradiation.

According to the examiner (see Office Action page 9, 11b.), Merrill discloses irradiation of polyethylene using electron irradiation while at a temperature above the melting temperature. Therefore, as clarified above, a combination of Ashby and Merrill processes would not provide a method that requires:

- i) irradiation of a polyethylene of a compression molded hybrid material in order to provide a strong interface between polyethylene and the piece; and
- ii) heating of the hybrid material after irradiation in order to improve oxidative stability.

Since the results of irradiation of a medical implant having interfaces (such as a hybrid material) would not have been predictable to one of ordinary skill in the art, mere combination of irradiating polymeric material while at a temperature above the melt and adding a metal piece to the irradiated polymeric material would not make the claimed method obvious.

However, for additional clarity, applicants amend the independent claims 1, 43, and 59 to recite "thereby forming a strong interface between the polyethylene and the piece". For support, see specification (for example, page 12, lines 1-8; paragraph bridging pages 12 and 13; page 21, lines 18-19; and page 22, lines 13-15; Figures 2, 4, and 5) that clarifies certain embodiments of the invention, for example, a surface with geometries (for example, mesh, recess, undercuts, grooves (see Figures 4 and 5), or the like) that allowed the polyethylene resin powder to penetrate, consolidate and take the shape of the surface such that the mechanical interlocking is achieved and resulted into a hybrid component having strong interlocking interface (see Figure 1). It is also clarified in the specification that because the shape memory of the compression molded polymer is set at the mechanically interlocked interface and that memory is strengthened by the crosslinking step, there is no significant separation at the interface between the polyethylene and the counterface (see specification, pages 12 and 13; Examples 1 and 2, Figures 2, 3, 4 and 5, for example).

The claimed methods provide a hybrid material having a strong interface. A strong interface refers to an interface of sufficient strength to withstand applied forces while the material is in the body so as to avoid significant separation at the interface

between the polyethylene and the counterface (see specification, pages 12 and 13; Examples 1 and 2, Figures 2, 3, 4 and 5, for example). The strength is such that the material will avoid disassociation following post-irradiation melting (see specification, page 25; Example 6, Figures 9 and 10, for example). Separation would result in implant failure and require revision surgery on the patient.

Applicants further refers to the arguments presented in the previous response, filed February 13, 2009, that the references cited by the examiner are not combinable without proscribed hindsight. For example, the method steps of: a) compression molding of polyethylene powder to a piece, thereby forming an interlocked hybrid material having an interface between the compression molded polyethylene and the piece; b) crosslinking the compression molded polyethylene portion of the hybrid material by ionizing radiation, thereby forming a strong interface between the polyethylene and the piece; and c) reducing free radicals in the crosslinked polyethylene by heating the hybrid material above the melting point of the crosslinked polyethylene, as discussed above, would be based on the knowledge gleaned only from the instant disclosure, and not obtainable through a fair reading of the prior art. Such a reconstruction is clearly improper. *In re McLaughlin* 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971).

Moreover, even if the cited references (Ashby, Merrill, Johnson, Kagiya, and/or Patel) are combined, as discussed above and in the previous response, would not provide methods that require: i) irradiation of a polyethylene of a compression molded hybrid material in order to provide a strong interface between the polyethylene and the piece; and ii) heating of the hybrid material after irradiation in order to improve oxidative stability. Also, even if the cited references are combined, would not yield the claimed medical implant.

Therefore, in view of the above, applicants request withdrawal of the obviousness rejection.

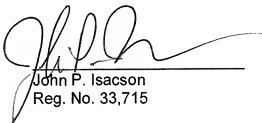
***Claim Objection:***

On page 9 of the Office Action, the examiner objects to claim 3 for improper antecedent basis. Applicants amend claim 3 to be dependent of claim 2. Withdrawal of the objection is therefore solicited.

**REQUEST**

Applicants submit that claims 1-6, 12, 15, 16, 43, 47, 48, and 59-61 are in condition for allowance and request consideration to that effect. The examiner is invited to contact the undersigned at (202) 628-6600 should there be any questions.

Respectfully submitted,



John P. Isaacson  
Reg. No. 33,715

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Date

PERKINS COIE LLP  
607 Fourteenth Street, N.W.  
Washington, D.C. 20005  
Phone: 202-628-6600  
Customer No. 61263